CLAIMS

1. A method for preparing a timeline for a clinical trial, comprising the steps of:

providing a machine readable protocol database, said protocol database identifying a sequence of workflow tasks for a first clinical trial protocol; and

in dependence upon said protocol database, automatically generating a timeline of expected patient progress through at least a portion of said workflow tasks during a first clinical trial to be conducted according to said first clinical trial protocol.

2. A method according to claim 1, wherein said timeline of expected patient progress is forward-looking.

3. A method according to claim 1, wherein said step of automatically generating comprises the step of generating said timeline in dependence upon actual patient progress through said portion of workflow tasks during a previous execution of a clinical trial according to said first clinical trial protocol.

4. A method according to claim 1, wherein said step of providing a machine readable protocol database comprises the step of copying said portion of workflow tasks from a prior clinical trial protocol,

and wherein said step of automatically generating comprises the step of generating said timeline in dependence upon actual patient progress through said portion of workflow tasks during a previous execution of a clinical trial according to said previous clinical trial protocol.

5. A method according to claim 1, wherein said step of automatically generating comprises the step of developing said timeline in dependence upon the simulated progress of a first hypothetical patient through said portion of said workflow tasks.

6. A method according to claim 5, wherein said step of developing said timeline is performed further in dependence upon the actual progress of a first actual patient through at least a portion of said workflow tasks.

7. A method according to claim 5, further comprising the step of automatically re-generating a timeline of expected patient progress through at least a portion of said workflow tasks, in dependence upon the actual progress of a first actual patient through at least a portion of said workflow tasks.

8. A method according to claim 1, wherein said workflow tasks include both patient management tasks and data management tasks.

9. A method according to claim 1, wherein said workflow tasks are grouped into a plurality of patient contact events, each of said patient contact events having associated therewith at least one of said workflow tasks,

and wherein said protocol database identifies a sequence of workflow tasks at least in part by identifying a sequence of said patient contact events.

10. A method according to claim 9, wherein at least one of said patient contact events includes an office visit.

11. A method according to claim 9, wherein said protocol database identifies said sequence of patient contact events at least in part by organizing said patient contact events as a workflow graph.

12. A method according to claim 1, wherein said protocol database identifies a plurality of stages in said sequence of workflow tasks,

and wherein said step of automatically generating comprises the step of predicting the number of patients who will be in each of said stages at a given point in time.

13. A method according to claim 12, wherein said stages include a treatment stage and a follow-up stage.

14. A method according to claim 1, wherein said step of automatically generating comprises the step of predicting the number of patients who will have completed their participation in said first clinical trial at a given point in time.

15. A method according to claim 1, wherein said step of automatically generating comprises the step of predicting a last patient, last patient contact date for said first clinical trial.

16. A method according to claim 1, wherein said protocol database identifies a plurality of stages in said sequence of workflow tasks, and wherein said step of automatically generating comprises the steps of:

predicting the best case number of patients who will be in each of said stages at a given point in time; and

predicting the worst case number of patients who will be in each of said stages at a given point in time.

17. A method according to claim 1, wherein said step of automatically generating includes the step of predicting the progress of said first clinical trial in response to the simulated progress of an assumed typical patient through at least said portion of said workflow tasks.

18. A method according to claim 1, wherein said step of automatically generating includes the step of predicting the progress of said first clinical trial in response to the simulated

progress of a plurality of hypothetical patients through at least said portion of said workflow tasks.

19. A method according to claim 18, wherein said plurality of hypothetical patients includes:

a first hypothetical patient assumed to progress most slowly through said portion of workflow tasks, and

a second hypothetical patient assumed to progress most quickly through said portion of workflow tasks.

20. A method according to claim 18, wherein said plurality of hypothetical patients includes:

a first hypothetical patient assumed to progress through said portion of workflow tasks at a rate which is no slower than a predetermined percentage of patients participating in said first clinical trial, and

a second hypothetical patient assumed to progress through said portion of workflow tasks at a rate which is no faster than said predetermined percentage of patients participating in said first clinical trial.

21. A method according to claim 1, wherein said sequence of workflow tasks is organized as a workflow graph having a plurality of alternative paths to a common destination node,

and wherein said step of automatically generating a timeline of expected patient progress through a portion of said workflow tasks comprises the step of making an assumption about how likely it is that a first hypothetical patient will follow each of said alternative paths.

22. A method according to claim 21, wherein said step of making an assumption is dependent upon the simulated prior progress of said first hypothetical patient through said workflow tasks.

23. A method according to claim 1, further comprising the steps of:

modifying said machine readable protocol database; and

in dependence upon said modified protocol database, automatically generating a revised timeline of expected patient progress through said portion of said workflow tasks.

24. A method according to claim 23, further comprising the step of displaying said revised timeline in conjunction with the timeline generated in dependence upon the unmodified protocol database.

25. A method according to claim 23, comprising the step of iteratively modifying said machine readable protocol database and automatically generating revised timelines, until an acceptable timeline is generated.

26. A method according to claim 23, wherein said step of modifying said machine readable protocol database is dependent upon actual patient progress experience through said portion of said workflow tasks.

27. A method according to claim 1, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

wherein said machine readable protocol database identifies typical time periods between said protocol path elements,

and wherein said step of automatically generating comprises the step of simulating the progress of a first hypothetical patient through said portion of said workflow tasks in dependence upon said typical time periods.

28. A method according to claim 1, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

wherein said machine readable protocol database identifies minimum and maximum expected time periods between said protocol path elements,

and wherein said step of automatically generating comprises the step of simulating the progress of first and second hypothetical patients through said portion of said workflow tasks in dependence upon said minimum and maximum expected time periods, respectively.

29. A method according to claim 1, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

wherein said machine readable protocol database identifies first and second expected time periods between each sequential origin and destination pair of said protocol path elements, the first expected time period being the time expected for a first predetermined fraction of participating patients to progress from the origin protocol path element of the pair to the destination protocol path element of the pair, and the second expected time period being the time expected for a second predetermined fraction of participating patients to progress from the origin protocol path element of the pair to the destination protocol path element of the pair,

and wherein said step of automatically generating comprises the step of simulating the progress of first and second hypothetical patient through said portion of said workflow tasks in dependence upon said first and second expected time periods, respectively.

30. A method according to claim 1, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

wherein said machine readable protocol database identifies probability distributions of the expected time periods between said protocol path elements,

and wherein said step of automatically generating comprises the step of simulating the progress of a first hypothetical patient through said portion of said workflow tasks in dependence upon said probability distributions.

31. A method according to claim 1, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

wherein said machine readable protocol database identifies first expected time periods between said protocol path elements,

further comprising the step of pre-calculating an expected duration for a first protocol phase in dependence upon said first expected time periods within said first protocol phase,

and wherein said step of automatically generating comprises the step of simulating the progress of a first hypothetical patient through said portion of said workflow tasks in dependence upon said pre-calculated expected duration for said first protocol phase.

32. A method according to claim 31, further comprising the step of pre-calculating an expected duration for a second protocol phase in dependence upon said first expected time periods within said second protocol phase,

and wherein said step of automatically generating comprises the step of simulating the progress of a first hypothetical patient through said portion of said workflow tasks further in dependence upon said pre-calculated expected duration for said second protocol phase.

33. A method according to claim 31, wherein said expected time periods between protocol path elements represent typical time periods.

34. A method according to claim 33, wherein said machine readable protocol database further identifies second expected time periods between said protocol path elements,

and wherein said step of pre-calculating an expected duration is performed further in dependence upon said second expected time periods between said protocol path elements.

35. A method according to claim 1, wherein said step of automatically generating occurs in dependence upon an assumed study site commencement timeline.

36. A method according to claim 35, further comprising the step of providing said assumed study site commencement timeline in dependence upon expert assessment.

37. A method according to claim 35, further comprising the step of providing said assumed study site commencement timeline in dependence upon historical information about the commencement time of a prior-begun study by a study site expected to participate in said first clinical trial.

38. A method according to claim 35, wherein said site commencement timeline includes an assumed number of participating study sites.

39. A method according to claim 35, wherein said site commencement timeline includes an assumed setup time for each participating study site.

40. A method according to claim 35, wherein said assumed study site commencement timeline represents a typical expected study site commencement time for a hypothetical study site.

41. A method according to claim 35, wherein said assumed study site commencement timeline includes expected best and worst case study site commencement times.

42. A method according to claim 35, wherein said assumed study site commencement timeline identifies a first time period within which a first predetermined fraction of the participating study sites are expected to commence said first clinical trial, and a second time

period within which a second predetermined fraction of the participating study sites are expected to commence said first clinical trial.

43. A method according to claim 35, wherein said assumed study site commencement timeline includes a probability distribution identifying, for each given study site expected to participate, the probability that the given study site will commence said first clinical trial at various times.

44. A method according to claim 35, further comprising the steps of:

modifying said assumed study site commencement timeline in dependence upon the actual study site commencement time of a first study site participating in said first clinical trial; and

in dependence upon said modified study site commencement timeline, automatically generating a revised timeline of expected patient progress through said portion of said workflow tasks.

45. A method according to claim 1, wherein said step of automatically generating occurs in dependence upon an assumed patient enrollment timeline.

46. A method according to claim 45, further comprising the step of providing said assumed patient enrollment timeline in dependence upon expert assessment.

47. A method according to claim 45, further comprising the step of providing said assumed patient enrollment timeline in dependence upon historical information about the patient enrollment timeline of a prior-begun study by a study site expected to participate in said first clinical trial.

48. A method according to claim 45, further comprising the step of providing said assumed patient enrollment timeline in dependence upon a typical expected patient enrollment timeline for a hypothetical study site.

49. A method according to claim 45, wherein said assumed patient enrollment timeline includes expected best and worst case patient enrollment timeline aspects.

50. A method according to claim 45, wherein said assumed patient enrollment timeline identifies a first time period within which a first predetermined fraction of the patients expected to be enrolled in said first clinical trial at a given study site are expected to have done so, and a second time period within which a second predetermined fraction of the patients expected to be enrolled in said first clinical trial at said given study site are expected to have done so.

51. A method according to claim 45, wherein said assumed patient enrollment timeline includes a probability distribution identifying, for a given study site, the probability that the given study site will have enrolled various numbers of patients in said first clinical trial by a given time.

52. A method according to claim 45, further comprising the steps of:

modifying said assumed patient enrollment timeline in dependence upon the actual patient enrollment experience during execution of said first clinical trial; and

in dependence upon said modified patient enrollment timeline, automatically generating a revised timeline of expected patient progress through said portion of said workflow tasks.

53. At least one computer readable medium collectively carrying a machine readable protocol database identifying:

a sequence of workflow tasks for a first clinical trial protocol; and

a value indicating an expected time period between performance of a first one of said workflow tasks for a given patient and performance of a second one of said workflow tasks for said given patient.

54. A medium according to claim 53, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

and wherein said machine readable protocol database identifies expected time periods between each sequential origin and destination pair of said protocol path elements.

55. A medium according to claim 54, wherein said plurality of protocol path elements are organized to include a plurality of alternative paths from a beginning protocol path element to an ending protocol path element,

and wherein said machine readable protocol database identifies a relative pathweight for each of said paths.

56. A medium according to claim 53, wherein said workflow tasks include both patient management tasks and data management tasks.

57. A medium according to claim 53, wherein said workflow tasks are grouped into a plurality of patient contact events, each of said patient contact events having associated therewith at least one of said workflow tasks,

and wherein said protocol database identifies said sequence of workflow tasks at least in part by identifying a sequence of said patient contact events.

58. A medium according to claim 57, wherein at least one of said patient contact events includes an office visit.

59. A medium according to claim 57, wherein said protocol database identifies said sequence of patient contact events at least in part by organizing said patient contact events as a workflow graph.

60. A medium according to claim 53, wherein said protocol database identifies a plurality of stages in said sequence of workflow tasks.

61. A medium according to claim 60, wherein said stages include a treatment stage and a follow-up stage.

62. A medium according to claim 53, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

wherein said expected time value represents a typical time period.

63. A medium according to claim 53, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

wherein said expected time value represents a minimum time period,

and wherein said machine readable database further identifies a maximum expected time period between performance of said first workflow task for said given patient and performance of said second workflow task for said given patient.

64. A medium according to claim 53, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

and wherein said machine readable protocol database identifies first and second expected time periods between each sequential origin and destination pair of said protocol path elements, the first expected time period being the time expected for a first predetermined fraction of participating patients to progress from the origin protocol path element of the pair to the destination protocol path element of the pair, and the second expected time period being the time

expected for a second predetermined fraction of participating patients to progress from the origin protocol path element of the pair to the destination protocol path element of the pair.

65. A medium according to claim 53, wherein said sequence of workflow tasks includes a plurality of protocol path elements,

and wherein said machine readable protocol database identifies probability distributions of the expected time periods between said protocol path elements.

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